Attachment 2

Non-technical abstract:

Background:

Vascular endothelial growth factor is a very powerful substance, known as a protein, which is produced and released naturally by the body when there is inadequate blood supply to an organ or tissue. This protein causes the growth of new blood vessels from existing vessels. Many studies have been performed in animals which have demonstrated that the delivery of the vascular endothelial growth factor protein causes a significant increase in blood flow to organs, including the heart. More recent studies in humans have begun to investigate the use of the gene that makes the vascular endothelial growth factor protein. By injecting this gene directly into the muscles of the leg, one group of researchers has been able to improve blood flow and wound healing in the rest of the affected limb. We believe that this method of treatment may also apply to patients with poor blood supply to the heart. In this study gene therapy will be delivered with a virus that has been altered to be incapable of causing disease. The virus assists in transporting the gene into the cells of the heart.

You have been invited to participate in this study because you have been diagnosed as having advanced coronary artery disease resulting in severe limitation of ordinary physical activity which cannot be treated with coronary artery bypass surgery or other coronary intervention such as balloon angioplasty or stenting.

Purpose:

The purpose of this study is to determine whether CI-1023 (a form of vascular endothelial growth factor) injected directly into the heart muscle through minimally invasive surgery will improve blood supply to the heart resulting in improved heart function when compared to medical therapy and to determine its safety. Vascular endothelial growth factor is a protein which causes the growth of new blood vessels from existing vessels.

Approximately 70 patients will be enrolled into this study from approximately 15 sites across Canada.

Evaluation:

The main evaluation of the effectiveness of the treatment will be made primarily by testing the ability of the patients to perform exercise. A comprehensive panel of tests will be performed to evaluate the risks and to ensure safety of this procedure.